

### **REMARKS**

Review and reconsideration of the non-final Office Action mailed February 25, 2008 (hereinafter "Office Action"), is hereby requested in view of the following remarks. At the time of the Office Action, claims 1-11 and 13-21 were pending. By this Amendment, claims 1, 6, 11, 18, 19 and 21 are amended. No new matter is added.

#### **Claim Rejections -35 U.S.C. § 103(a)**

In the Office Action, claims 1-5, 11, 14-17 and 21 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2005/0100640 filed by Pearce (hereinafter "Pearce") in view of U.S. Patent No. 4,241,092 issued to Halik *et al.* (hereinafter "Halik") and further in view of U.S. Patent No. 5,286,496 issued to Stapler *et al.* (hereinafter "Stapler"). Applicants respectfully submit that the cited references fail to disclose or suggest the claimed spherical coated capsule or the unexpected properties exhibited by the claimed spherical coated capsules.

Prior to addressing the cited references, Applicants wish to review the claimed invention. As set forth in amended claim 1, the claimed spherical coated capsule is drawn to:

1. (currently amended) A spherical coated capsule comprising
  - (a) a liquid or viscous core,
  - (b) a seamless shell surrounding this core, and
  - (c) a seamless, solid coating on said shell, wherein
    - the diameter of the coated capsule is in the range of 5 - 9 mm,
    - the solid coating comprises at least one sugar or sugar-alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule,
    - the diameter of the shell is in the range of 3 - 7 mm,
    - the thickness of the shell is in the range of 20 -200  $\mu$ m,
    - the ratio of shell thickness to shell diameter is in the range of 0.004:1 - 0.04:1 ,
    - the shell contains 70 - 90 % (m/m) gelatine or alginate and 10 - 30 % (m/m) of a plasticizer, based on the solids content of said shell, and
    - the core has a flavouring content in the range of 1 - 100 % (m/m), based on the total mass of the core, wherein the plasticizer is selected from the group that consists of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof.

Of particular interest for the following discussion, the claimed spherical coated capsule includes a shell that contains "70 - 90 % (m/m) gelatine or alginate and 10 - 30 % (m/m) of a plasticizer, based on the solids content of said shell, ... wherein the plasticizer is selected from the group that consists of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof." Applicants note that the plasticizer that constitutes 10-30% of the shell must be a polyol or a mixture of polyols. In addition, the seamless solid coating includes at least one sugar or sugar alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule. In combination with the remaining claim limitations, the claimed spherical coated capsules unexpectedly (a) do not have a disturbing haptic effect, (b) dissolve rapidly, and (c) are not sticky or tacky. These unexpected results occur, in part, because the shell and the seamless, solid coating are carefully adapted to one another.

Pearce is drawn to any number of edible articles, including numerous embodiments produced by laminating film layers together, *e.g.*, softgels. *See* Pearce, Paragraph [0325]-[0326]. Pearce discloses that the films can include 10-90 wt-%, preferably 25-75 wt-% of film forming agents, any number of plasticizers, including polyols, and other ingredients. *See* Pearce, Paragraph [0027]. While Pearce discloses that the general plasticizer content should be less than 20 wt-%, Pearce expressly states that the amount of polyols can range between 0.1 and 5% by weight. *See* Pearce, Paragraph [0027]. Applicants note that the claims require that the seamless coating contain 10-30% (m/m) of a polyol plasticizer, *e.g.*, one "selected from the group that consists of glycerol, propylene glycol, sorbitol, maltitol and combinations thereof." Thus, a person of ordinary skill in the art would understand that this teaches away from the claimed compositions, which contain 10-30% (m/m) of plasticizers selected from the group of polyol plasticizers consisting of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof.

Stapler is drawn to breath protection microcapsules. As indicated previously, Stapler does not provide any substantial disclosure regarding how the microcapsules are formed or the amounts and types of plasticizers and gelling agents found in the microcapsule shell. As previously acknowledged by the Examiner, "Stapler does not disclose the microcapsules being coated or gel points of the gelatin and plasticizer." Rather, the inventive aspect of Stapler is that both the core and the shell contain the same breath control or antimicrobial agents. Thus, Stapler does nothing to overcome the teaching of Pearce, which limits the presence of polyols to between 0.1 and 5% by

weight. *See* Pearce, Paragraph [0027].

Halik is drawn to a candy that includes granules of a gasified candy, *e.g.*, "Pop Rocks", dispersed in a binding matrix comprising crystallized sorbitol. Gasified candy produces a popping sound when exposed to moisture, so protection from moisture is necessary to achieving shelf life of the gasified candy product. Halik discloses that the gasified candy is embedded in a pure sugar film in order to prevent the gasified candy from being exposed to moisture prior to consumption. *See* Halik, col. 3, ln. 15 – col. 3, ln. 31. The gasified candy film is then rolled out and cut into discrete pieces, *e.g.*, "pillows." *See* Halik, col. 4, ln. 52 - col. 5, ln. 47. Halik then discloses that the sorbitol pillows may be coated using an edible shellac or varnish or hard sugar. *See* Halik, col. 5, ln. 61-63.

In contrast to Pearce, Stapler and the claimed spherical coated capsules, Halik is drawn to a solid sugar candy embedded in a film, which can be broken up and subsequently coated. The citations referenced in the Office Action do not acknowledge any difference between the embedding film and the coating. Rather, the Office Action asserts that the Halik disclosure apply to the seamless, solid coating applied on the shell.

For example, the Office Action refers to sorbitol as being the preferred coating material, as being a viscous glassy melt, and as being present in amounts up to 60 wt-%. Each of these references is to the embedding film, not to the coating that can be applied subsequently. Once formed, the solid sugar film with gasified candy embedded therein is cut into discrete pieces. *See* Halik, col. 5, ln. 23-60. Based on Halik, it is apparent that (1) these pieces do not include a liquid core, and (2) do not have the claimed dimensions. Accordingly, Halik is substantially different from the claimed spherical coated capsules.

As Halik does not relate to microcapsules in any manner, it must be recognized that the formation and handling of microcapsules with a liquid core and a very thin shell is a completely different problem than that addressed by Halik. Furthermore, the post-formation treatments disclosed in Halik merely disclose that such treatments can be applied to solid candy, not to microcapsules, such as the claimed spherical coated capsules.

Based upon a fair review of the cited references, it is clear that the cited references fail to disclose the claimed spherical coated capsules with a seamless shell containing (1) "70 - 90 % (m/m) gelatine or alginate and 10 - 30 % (m/m) of a plasticizer, based on the solids content of said shell,

... wherein the plasticizer is selected from the group that consists of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof," and (2) a seamless solid coating that includes "at least one sugar or sugar alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule." In fact, Pearce expressly teaches away from the claimed spherical coated capsules by unambiguously stating that polyols can range between 0.1 and 5 wt-%. *See* Pearce, Paragraph [0027]. There is simply nothing in the remaining references that overcomes this teaching away of the primary reference or that discloses or suggests that the claimed spherical coated capsules would have the unexpected properties of overcoming the deficiencies of the prior art. As none of the cited references suggest the claimed spherical coated capsule, Applicants submit that the rejection can only be supported by improper hindsight. Accordingly, Applicants respectfully request that the rejection based on Pearce, Halik and Stapler be withdrawn.

Applicants also wish to direct the Examiner to claim 11, which requires that the concentration of the plasticizer in the shell is 15 - 20 % (m/m) based on the total solids content of the shell. As noted previously, antecedent basis requires that the relevant plasticizer be a polyol selected from the group consisting of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof. Nothing in the cited references discloses or suggests including this amount of polyol plasticizers in the shell of a spherical coated capsule.

Another important feature of the claimed invention is the ability to provide a large diameter, thin shelled spherical coated capsule that is stable during manufacturing and handling but also dissolves rapidly, does not adhere to the teeth, and does not have a disturbing haptic effect in the mouth. Although the general class of coated capsules are well known in the art, it is equally well-known that there are abundant challenges remaining to develop coated capsules with specific properties. It is also well-known that small changes in ingredients and their amounts can have a substantial and unpredictable result on the properties of the shell and the interaction of the shell with the core or the shell with any coating deposited thereon. Prior to the Applicants' development of the claimed microcapsule, researchers had not successfully developed a shell-coating combination with the properties of the claimed spherical coated capsule: a large diameter, thin shelled spherical coated capsule that is stable during manufacturing and handling but that dissolves rapidly once in the mouth, does not adhere to the teeth, and does not have a disturbing mouthfeel. The Applicants were able to develop the claimed microcapsule, which

successfully provides these properties, using a unexpected combination of ingredients that is neither disclosed or suggested by the cited art, whether alone or in combination.

In contrast to the problem addressed by the claimed spherical coating capsule, the only disclosure in any cited reference that is even broadly related to the problem of the present invention is found in Pearce, paragraph [0088], which references “a powder to reduce tackiness.” However, this passage does not resolve the issue addressed by the claimed capsule, which is producing a coated seamless capsule that does not adhere to the teeth or produce an annoying haptic effect, *i.e.*, stickiness after the capsule is exposed to moisture. Rather, the only portion of Pearce's disclosure even remotely related to this problem pertains to preventing adherence to machinery or adjacent materials during production or shipping.

Adherent or tacky materials will adhere to surfaces of production machinery or packaging materials, thus creating unwanted residues and contamination. It is therefore necessary to prevent the material from adhering to these surfaces. This is conventionally done by adding a thin layer of powder, such as talc, to the material to reduce adherence. A example of this approach is chewing gum, which is sprinkled with white powder so that it does not adhere to the paper wrapping. However, these powder coatings cease to provide an anti-tackiness function once they are exposed to moisture.

Pearce acknowledges that the soluble films disclosed therein are adherent to one another and proposes dispensers as a solution, *see* Pearce, paragraphs [0150]-[0154]. Pearce does not suggest reformulating the film (shell) and providing a compatible coating to avoid adherence to both tissue and adjacent materials. What Pearce does disclose is that:

One problem is that the films are stacked, and sometimes become lightly adhered to one another, especially in humid environments. Even when not adhered, it can be difficult to slide the film out of the container while leaving the other films behind, because to be successful the method requires proper technique, dexterity, and involves the use of the finger which will vary in its friction characteristics from person to person and day to day, and will be seen as non-hygienic by some.

Pearce, paragraph [0150]. Thus, it is clear that Pearce's films are adherent, unlike the claimed spherical coated capsules.

The approach to solve the problem of adherence to adjacent materials or machinery does not generally have anything in common with approaches to reduce adherence to the teeth. A powder

applied to avoid adherence of an adherent substance, *e.g.*, gum, to a wrapper provides a physical barrier to prevent adherence. However, once chewing commences, this physical barrier is disrupted (dissolved in many cases) and cannot prevent adherence to the teeth or other oral tissues. Thus, if Pearce would have had in mind the problem of the present invention, he would not have proposed a solution that is obviously not applicable to the problem of the present invention but only applicable to the problem of reducing adherence to machinery.

The difference between the problem solved by Pearce and the problem of the claimed spherical coated capsule is also visible when considering that the claimed spherical coated capsules solve this problem, in part, by the provision of at least one sugar or sugar-alcohol in the solid coating. This produces a shell-coating complex that prevents adherence and an annoying mouthfeel. Pearce is completely silent about a seamless coating and the amount of sugar or sugar-alcohol, which is claimed as 30 - 90 % (m/m) based on the total mass of the claimed coated spherical coated capsule. It is a distinguishing feature identified by the inventors that instead of providing more of the talc powder to reduce tackiness to machinery, the problem of the present invention is instead solved by combining the claimed seamless shell with the solid, seamless coating, having the claimed ingredients in the claimed amounts. Thus, the elements of the claimed seamless coated capsule, *e.g.*, a shell comprising gelatine or alginate and plasticizer combined with a coating comprising a specified amount of sugar or sugar-alcohol - are carefully adapted to each other to overcome the problems of prior art. Applicants note that none of the cited references, whether alone or in combination, disclose or suggest this combination of ingredients.

The person skilled in the art is thus aware of the differences between reducing adherence to the teeth and reducing adherence to machinery. Thus, such a person would not have considered Pearce, which relates to a different field of art, for solving the problem of the present invention. Because the Pearce document does not pertain to the technical field of the invention, Applicants respectfully assert that Pearce cannot be combined with any of the cited references without improperly resorting to hindsight.

In addition, as noted above, the claimed spherical coated capsules unexpectedly avoid the deficiencies of the prior art because they (a) do not have a disturbing haptic effect, (b) dissolve rapidly, and (c) are not sticky or tacky. *See* Specification, Paragraph [0011]. With respect to unexpected results, the Specification also explains that prior to the claimed invention, "it has been

found to be disadvantageous that the majority of shells of ready-to-consume capsules available commercially are detectable as an unpleasant, rubbery, tough residue. Corresponding observations are made and found to be particularly negative especially in the case of larger filled capsules with diameter of about 4 mm." See Specification, paragraph [0005], subheading 1. For at least the above reasons, Applicants respectfully request that the rejection based on the combination of Pearce, Halik and Stapler.

Applicants note that there is ample case law standing for the proposition that unexpected results can be sufficient to overcome an obviousness rejection. For example, the Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness, see *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); MPEP 2145. In *In re Chupp*, the claims were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and corn, but average results for other crops, see *id.* at 644. The prior art was a homolog of the claimed compound and was disclosed as being a selective herbicide for crops generally.

The Court noted that the claimed compound's "superior activity in corn and soybeans is a new and unexpected property," *In re Chupp*, 816 F.2d at 645. The Commissioner argued that the claimed compound provided average selective herbicidal activity for many crops and poor herbicidal activity for others. The Federal Circuit responded to this argument by concluding that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was sufficient to rebut a *prima facie* case of obviousness, see *id.* at 646.

The Federal Circuit in *In re Rijckaert* explained that, "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established," 9 F.2d 1531, 1534 (Fed. Cir. 1993). See MPEP 2141.02.V. In this case, there is nothing in any of the cited references that suggests that the claimed combination of ingredients would produce the claimed spherical coated capsules which (a) do not have a disturbing haptic effect, (b) dissolve rapidly, and (c) are not sticky or tacky. Thus, in addition to failing to disclose or suggest the claimed spherical coated capsules, Applicants believe that the evidence of unexpected results would overcome any rejection established by the cited references.

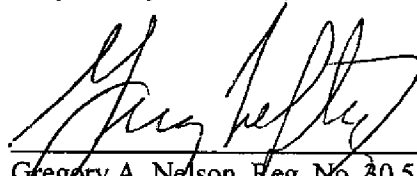
In the Office Action, claims 6-10, 13 and 18-20 were rejected under 35 U.S.C. § 103(a) as being obvious over Pearce in view of Halik and Stapler, in view of at least one of U.S. Patent No. 6,770,311 issued to Alamian *et al.* (hereinafter "Alamian") and U.S. Patent No. 5,378,131 issued to Greenberg *et al.* (hereinafter "Greenberg "). Applicants now address these references.

According to the Examiner, Alamian discloses that a skilled person would contemplate the use of gelatine, fish gelatine etc. and alginate for the production of microcapsules. However, the capsules described by Alamian are explicitly said to be caviar replacements. It is well-known that caviar is sticky. Thus, when trying to produce non-sticky microcapsules, the skilled person would not have contemplated the use of the materials mentioned in the Alamian reference since he would have to believe that these materials would render the microcapsules sticking to teeth, tongue etc.

#### Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,



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